EXHIBIT 1

Gynecare

TVT™ Obturator System

Tension-free Support for Incontinence

GYNECARE TVT™ obturatorsystem
Spændingsfri støtte til inkontinens

GYNECARE TVT™ obturatorsysteem
Spanningsvrij steunbandje tegen incontinentie

GYNECARE TVT™ -obturaattorijärjestelmä
Jännityksetön tuki inkontinenssin hoitoon

Système obturateur GYNECARE TVT™
Dispositif sans tension contre les incontinences

GYNECARE TVT™ Obturatorsystem
Spannungsfreie Unterstützung bei Inkontinenz

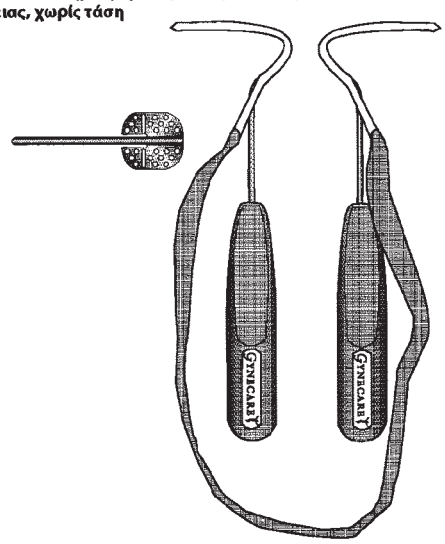
Sistema otturatorio GYNECARE TVT™
Dispositivo tension-free per l'incontinenza

Sistema obturador GYNECARE TVT™
Suporte sem tensão para incontinência

Sistema obturador GYNECARE TVT™
Protector sin tensión para la incontinencia

GYNECARE TVT™ obturatoriabandsystem
Spänningsfritt inkontinensstöd

Σύστημα επιπωματικού GYNECARE TVT™
Σύστημα υποστήριξης για την αντιμετώπιση της ακράτειας, χωρίς τάση



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P18070
LAB0010875v4
05/2014
Made in Switzerland
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ENGLISH

GYNECARE TVT™ Obturator System
Tension-free Support for Incontinence

GYNECARE TVT Obturator Device, Sterile Single Use

GYNECARE TVT Obturator Helical Passers, Sterile Single Use

GYNECARE TVT Obturator Atraumatic Winged Guide, Sterile Single Use

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:
This package insert is designed to provide instructions for use of the GYNECARE TVT™ Obturator System, including the GYNECARE TVT Obturator device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION
The GYNECARE TVT Obturator System is a sterile, single patient use procedure kit consisting of:

GYNECARE TVT Obturator device
The GYNECARE TVT Obturator device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phthalocyanine blue, Color Index Number 74160) PROLENE™ polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that provides elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT Helical Passers
The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT Obturator device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT Obturator device. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide
The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

INDICATIONS
The GYNECARE TVT Obturator device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

INSTRUCTIONS FOR USE
(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. If desired, retract the labia to provide additional exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. *(See Figure 1)*